

REMARKS

I. Introduction

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 5-6 and 11 are currently amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 1-12 will remain pending in the application.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Response to Issues Raised by Examiner in Outstanding Office Action

a. Claim Objections

Claim 6 is objected to for an incorrectly spelled word. Applicants have amended the claim and request withdrawal of the objection.

b. Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 5 is rejected under 35 U.S.C. § 112, second paragraph because there is insufficient antecedent basis. Applicants have amended the claim to provide proper antecedent basis and request reconsideration and withdrawal of the rejection.

c. Issues Under Double Patenting

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/343,008 ("the '008 patent"). Applicants note that provisional rejections based on this ground are provided for in the MPEP, but should be removed when the rejection is the only

rejection remaining in the application. See MPEP § 804. Applicants request removal of this rejection following reconsideration and withdrawal of the below rejections.

d. Claim Rejections - 35 U.S.C. § 102

Claims 1-3, 6-8 and 12 are rejected under 35 U.S.C. § 102(a) as being anticipated by Luo et al. (US Patent Application 2001/0051166). The Office asserts that Luo describes numerous elements found in the rejected claims. Office Action, pp. 3-4.

At the onset, Applicant notes that Luo does not deal with microemulsions according to the present application. In fact, the term, “microemulsion” does not appear in Luo.

Applicant wishes to clarify the definition of the term “microemulsion” in the present invention in order to avoid any misinterpretation or confusion with the term “emulsion,” such as provided in Luo. The term “microemulsion” was defined by Danielson and Lindman (Colloids Surfaces, 3:391, 1981) as follows: “A microemulsion is defined as a system of water, oil, and amphiphile which is a single optically isotropic and thermodynamically stable liquid solution”. Applicant wishes to emphasize the differences between emulsions and microemulsions: “emulsions” are not optically isotropic, are not thermodynamically stable, and are not spontaneously formed (i.e., needed energy for the dispersion process). It should also be noted that a mixture of oil, water and amphiphile must be well-designed with respect to proper molecular structures and weight ratios to form a microemulsion (i.e., many oils and amphiphiles can form emulsions with water but only a few can be selected to form microemulsions).

According to the present invention, for the first time, a microemulsion based on tetraglycol (glycofurol) as the co-surfactant has been prepared. Most microemulsions are formed with the aid of low-chain or medium-chain alcohols. However, until the present invention, no one has published an alcohol-free microemulsion which is formed using tetraglycol.

Therefore, the anticipation of the current invention based on Luo is traversed as Luo does not describe microemulsions and their formation according to the present invention. As a rejection under 35 U.S.C. § 102 must anticipate every limitation of the claim, Applicants

believe Luo does not anticipate claim 1. All of the remaining claims also require a microemulsion and are also not anticipated. Applicant respectfully requests reconsideration and withdrawal of the rejection.

e. Claim Rejections - 35 U.S.C. § 103

Claims 4-5 and 9-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Luo et al. in view of Sintov et al. (WO 02 09763). Applicant respectfully requests reconsideration and withdrawal of the rejection.

The Office asserts that Sintov discloses a transdermal delivery system in hydrogel form as well as certain guar based polymers and non-ionic surfactants. Office Action, pp. 5-6.

To establish a *prima facie* case of obviousness, there needs to be (1) some suggestion or motivation to modify the reference or to combine reference teachings, (2) a reasonable expectation of success, and (3) the prior art references, when combined, must teach or suggest all the limitations of the claimed invention. *See* MPEP §2143 (Aug. 2001). “Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant’s disclosure.” *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). Applicant respectfully asserts that the examiner has not met his burden.

As provided above, Applicant notes that the current claims require the use of microemulsions and Luo does not describe or suggest the use of these microemulsions. Similarly, Sintov does not deal with microemulsions and, therefore, can not teach that tetraglycol can create microemulsions according to the present invention. Consequently, both references, even viewed as a whole, can not make the current claims obvious because they do not teach every limitation of the claimed invention. In light of the above, Applicant respectfully requests reconsideration and withdrawal of the rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant(s) hereby petition(s) for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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